

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* * * * *

JEREMY EAMICK, *

*

Petitioner, *

No. 15-519V

*

Special Master Christian J. Moran

v. *

*

Filed: May 15, 2018

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

*

Entitlement, hepatitis A vaccine,

*

hepatitis B vaccine, GBS, cytokines,

Respondent. *

concurrent illness.

* * * * *

Edward M. Kraus, Law Offices of Chicago Kent, Chicago, IL, for petitioner;

Lisa Ann Watts, United States Dep't of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Petitioner, Jeremy Eamick, alleges that the hepatitis A and hepatitis B vaccines that he received on June 15, 2012 and July 17, 2012, caused him to develop the Miller-Fisher variant of Guillain-Barré syndrome ("GBS").² Mr. Eamick is seeking compensation pursuant to the National Childhood Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa-10 through 34 (2012).

The parties do not dispute that an upper respiratory infection ("URI") affecting Mr. Eamick in the month leading to the onset of his GBS was a but-for

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

² Miller-Fisher syndrome is a variant of GBS that is found in a small subset of the United States GBS population. Tr. 72, 101. For the purposes here, Mr. Eamick's condition is referred to as GBS since, according to petitioner, the fact that his GBS was of the Miller-Fisher variant is not important to his theory of causation. Tr. 73, 76.

cause of his GBS. However, petitioner's expert, Dr. Eric Gershwin, adds that the infection was not sufficient to cause Mr. Eamick to develop GBS and that it was the vaccines that transformed the relatively ubiquitous URI into an infection that ultimately caused Mr. Eamick to develop GBS. Respondent's expert, Dr. Penelope Morel, disagrees. She argues that Mr. Eamick's URI was sufficient to cause his GBS.

Under the framework for determining causation promulgated by the Federal Circuit, Mr. Eamick has met his burden for proving entitlement to compensation. Mr. Eamick presents a logical sequence of cause and effect connecting the vaccination and the injury, which is based on a persuasive medical theory and a showing that the temporal sequence is appropriate. Further, the Secretary has not established that a factor unrelated to the vaccination is the cause of Mr. Eamick's symptoms.

I. Facts

The facts of Mr. Eamick's case are not in dispute. Mr. Eamick was 33 years old when he developed GBS in July 2012. The month before, Mr. Eamick reported for basic training in the Army National Guard. Exhibit 1 at 6. As part of his service, Mr. Eamick received vaccines for adenovirus 4 and 7, bicillin, hepatitis A and hepatitis B, meningococcal, polio IPV, and tetanus-diphtheria-pertussis on June 15, 2012. Exhibit 11 at 1. Three weeks later, on July 7, 2012, Mr. Eamick went to the clinic with complaints of congestion, cough, and sinus discharge. Exhibit 8 at 54. Ten days following this visit, on July 17, 2012, Mr. Eamick was vaccinated again with the second administration of the hepatitis A and hepatitis B vaccines. Exhibit 11 at 1. During this time, Mr. Eamick's respiratory infection had been progressively worsening and he reported to the clinic again on July 21, 2012. Exhibit 8 at 50. At this visit, he was diagnosed with bronchitis and was prescribed an antibiotic. Id.

Dr. Gershwin and Dr. Morel agree that Mr. Eamick's GBS first manifested on July 24, 2012. Tr. 108, 200. On that date, he went to the emergency department at Fort Leonard Wood Hospital complaining of difficulty speaking, difficulty with coordination, and numbness in his face, hands, and feet. Exhibit 1 at 39. He was discharged and ordered to bed rest. Id. at 43. He returned to the same hospital the next day when he had difficulty walking and performing his duties. Id. at 44-45. The hospital diagnosed him with an acute neurological injury. Exhibit 8 at 7. The hospital also recommended that Mr. Eamick be sent to the

University of Missouri Hospital, which he was later that same day, July 25, 2012. Id.; exhibit 1 at 53.

Mr. Eamick was hospitalized at the University of Missouri hospital for longer than two weeks. See exhibit 2. Testing found anti-GQ1b antibodies, which confirmed a diagnosis of GBS.³ Id. at 68. Although Mr. Eamick received extensive care, including plasmapheresis and physical therapy, he continues to experience disability due to the GBS. See exhibit 12 at 1-5. Both experts characterized Mr. Eamick's case to be a particularly severe form of GBS. Tr. 96, 184.

Mr. Eamick filed his petition for compensation on May 21, 2015. On November 4, 2015, respondent filed his Rule 4(c) report, stating that there was, among other deficits, insufficient evidence linking vaccinations to GBS. See Resp't's Rep., filed Nov. 4, 2015, at 7-10.

Mr. Eamick filed two reports from Dr. Gershwin in support of his claim for compensation (exhibits 25 and 113). The Secretary filed two responsive reports from Dr. Morel (exhibits B and DD).⁴ A one-day entitlement hearing was held on September 13, 2017. Mr. Eamick, Dr. Gershwin, and Dr. Morel testified in the hearing.

II. The Experts' Qualifications and Assessment

A. Dr. Eric Gershwin, M.D.

Dr. Gershwin is a Distinguished Professor of Medicine with the University of California at Davis, where he currently holds a chaired professorship in honor of Jack and Donald Chia. Dr. Gershwin received his undergraduate degree, summa cum laude, from Syracuse University and his medical degree from Stanford. He has an honorary doctorate from the University of Athens, in recognition for his lifetime contribution in immunology and medicine. He has also been awarded the AESKU prize in Autoimmunity in 2008, in recognition of his lifetime contribution in immunology. He is also fellow with the American Association for the Advancement of Science. He is board-certified in internal medicine, rheumatology, and allergy and clinical immunology, and currently serves as the

³ See generally exhibit 58 for a discussion of how antibodies to gangliosides (molecular structures present on neurons)—such as GQ1b—mediate the course of GBS.

⁴ Ancillary reports from the experts addressing specific questions were also filed by both petitioner and respondent.

editor-in-chief for the Journal of Autoimmunity, Autoimmunity Reviews, and Clinical Reviews in Allergy. He has written or edited 68 books or monographs, approximately 1,000 experimental research articles, 160 book chapters, and 200 review articles.

B. Dr. Penelope Morel, M.D.

Dr. Morel is a professor in the Department of Immunology at the University of Pittsburgh, with a secondary appointment as a professor in the Department of Medicine. She also serves as an affiliate member in the Center for Vaccine Research. Dr. Morel received her undergraduate and medical degrees from the University of Southampton in the United Kingdom. She obtained her doctor of medicine in immunology from the University of Geneva in Switzerland. While she performed clinical work early in her career, she no longer practices medicine and does not hold any board certifications. Tr. 176. Dr. Morel has published approximately 70 experimental research articles, and 40 non-experimental articles, chapters, and reviews.

C. Evaluation

In considering the value of opinion testimony, special masters may consider the offeror's expertise and weigh the opinion accordingly. Copenhaver v. Sec'y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436, at *7 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016). Beyond expertise, special masters may make determinations as to the credibility of the persons presenting opinion evidence. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1326 (Fed. Cir. 2010).

While both experts provided helpful testimony, Dr. Gershwin's testimony was considerably more impressive. Dr. Gershwin's testimony struck the undersigned as being highly credible. He appeared confident in the opinions he did express, but at the same time he was candid and forthright when stating the limits of those opinions and the stochastic nature of topics being discussed. In addition, Dr. Gershwin's experience and expertise as both a physician and a scientist allowed him to provide helpful insight into the questions at issue. Finally, Dr. Gershwin's scholarship is broad; few experts in the Vaccine Program have written as prodigiously as he has. His expansive knowledge in the field of autoimmunity gave substantial weight to his opinions.

Compared to Dr. Gershwin, Dr. Morel's answers were often uncertain in both tone and content. While Dr. Morel is medically trained, she has not treated patients in some time and this lack of practical experience, accordingly, limited the weight and scope of some of her opinions. While Dr. Morel's scholarship is impressive, the scope of her scholarship and reputability in the field of immunology has not yet reached the level of Dr. Gershwin. This may very well reflect that she is at an earlier stage of her career compared to Dr. Gershwin, but that does not affect the ultimate impression that Dr. Gershwin's opinion carries with it more weight on topics in immunology.

III. Standards for Adjudication

Compensation under the Vaccine Act is available in two major forms. Table injuries, which presume causation, can be established if a prescribed injury occurs during a set period of time following a specific vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Alternatively, petitioners can receive compensation for injuries not provided for in the Vaccine Injury Table by bringing a successful petition for compensation under 42 U.S.C. § 300aa-11(c)(1)(C)(ii) of the Vaccine Act.

Here, Mr. Eamick does not claim that GBS constitutes a Table injury for hepatitis A or B vaccine under the Vaccine Act. As an "off-Table Injury," Mr. Eamick must demonstrate that the vaccination caused his injury.

Petitioner's burden of proof as an off-Table injury is explicitly defined by Congress. The Act provides that a petitioner must show, by a preponderance of the evidence, that the vaccination caused or significantly aggravated his illness or injury. See 42 U.S.C. § 300aa-13(a)(1) and 42 U.S.C. § 300aa-11(c); see also Moberly, 592 F.3d at 1322 (noting that petitioners must prove causation by the traditional tort standard of preponderance). As for what is specifically required to meet this burden, the statute requires that the conclusion of the court or special master may not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). The statute does not speak to the strength or reputability of the medical opinion, just that a medical opinion or medical records are necessary for a claim to be meritorious. See id.

In drawing conclusions on causation, the Federal Circuit has noted that special masters must be careful not to raise petitioners' burden by establishing tests that create requirements not in the statute itself. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (rejecting a test that required

“epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities”); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005) (rejecting a test requiring “confirmation of medical plausibility from the medical community and literature” to prove causation in fact); Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) (“to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program”).

Instead, special masters must consider all the evidence and decide whether the causal link between the vaccination and the injury was logical and legally probable. See Knudsen, 35 F.3d at 549 (“The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [] injury.”); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (“Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.”); Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991) (“causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.”).

In determining whether preponderant evidence exists, the Federal Circuit has set forth a three-part framework for evaluating claims of vaccine injury causation. As explained in Althen, and subsequent opinions, petitioners must put forth: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

IV. Analysis

A. Althen Prong One: Petitioner's Medical Theory.

Mr. Eamick does not need to prove with scientific certainty that the vaccination he received can cause GBS. However, petitioners may not posit just any theory of causation; the theory must be “reputable.” Althen, 418 F.3d at 1278 (“A persuasive medical theory . . . being supported by reputable medical or scientific explanation”) (internal citations omitted). What makes a theory “reputable” is not exactly clear. In Hibbard, the Federal Circuit stated that petitioner's burden was to provide a “viable medical theory by which a vaccine can cause the injury claimed by the petitioner.” Hibbard v. Sec'y of Health & Human

Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012). In contrast to mere “viability,” in Moberly, the Federal Circuit required that the theory be “legally probable.” Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010). Though the Federal Circuit has not spoken in unison about what exactly is required from petitioners, based on the directives it has provided, it appears accurate to say that petitioner’s medical theory linking the vaccination and the injury must, at the least, be consistent with what is known about human biology. Without a theory that passes that barrier, the Federal Circuit dictates that compensation should be precluded. If the theory meets this minimum barrier to entry, the special master should proceed to consider the other Althen elements to make an ultimate conclusion on the question of whether predominant evidence exists to find causation.

To understand the experts’ positions as it relates to Mr. Eamick’s case, a brief review of Mr. Eamick’s condition and its etiology is useful. GBS is a potentially life-threatening disease hallmarked by weakness in the extremities. Exhibit E at 1. Some cases, as in Mr. Eamick’s, result in respiratory distress. Id. Scientists believe that GBS is autoimmune in nature and results from the body’s immune system generating crossreactive antibodies formed in response to pathogen-borne antigens. See id. at 1-4. These antibodies will then attack nerve membranes, resulting in nerve damage or a loss of nerve conduction. Id. This attack on the body’s own cells is referred to as a “loss of tolerance.”

As noted before, the creation of the cross-reactive antibodies is usually the result of exposure to certain pathogens. Id. at 3. Some pathogens will result in GBS more frequently than others. Id. Although the most common is *Campylobacter jejuni*, a gastrointestinal infection, upper respiratory infections, such as the infection that Mr. Eamick had, are another common culprit. Id.

It is not known why some URIs develop into GBS while most do not. Dr. Gershwin cites from exhibit 51 (Hadden) for the proposition that the reason some infections result in GBS is likely a function of how the body’s immune system responds to the infection as opposed to features of the infection itself. Tr. 82. Specifically, he references the authors’ statement that “[t]he pathogenesis is likely to depend not only on the immunogenic components of the infecting organisms, but also on the host's immune response.” Id. (referencing exhibit 51 (R.D.M. Hadden et al., Preceding Infections, Immune Factors, And Outcome In Guillain-Barre Syndrome, 56 *Neurology* 758 (2001)) at 7). Importantly, Dr. Morel, agreed with this proposition in her testimony. See Tr. 247-48.

Dr. Gershwin, in his reports and his testimony, provided a persuasive case for how the hepatitis vaccines could dysregulate the host's response to the URI infection in a way that resulted in a breach of tolerance. Dr. Gershwin argued that cytokines are already known to act as "amplifiers" that "facilitate antigen presentation" by "augmenting . . . antibody production." Tr. 76-77. This cytokine response plays a necessary role in developing Mr. Eamick's immune response to the URI. A similar type of cytokine response happens as a result of all vaccinations. Tr. 88. In Dr. Gershwin's estimation, this cytokine response from the vaccination can have non-specific effects. Specifically, it can, in conjunction with the immune response to the URI, result in a loss of tolerance to endogenous antigens through molecular imitation of the URI antigen. Tr. 85, 89. This crossreactivity is what ultimately leads to GBS. Tr. 89.

The Secretary's expert, Dr. Morel, attempted to rebut Dr. Gershwin's theory on three main grounds. First, she argues that the cytokine response to the vaccine could not have interacted with the response to the URI since the cytokine response to the vaccine is limited in space and does not result in a systemic cytokine response. Tr. 188. Second, she argues that the epidemiological evidence does not support causation. Third, she argues that there is no evidence in support of Dr. Gershwin's theory. Tr. 183-84. These critiques are addressed in turn.

Dr. Morel argues that "there would have to have been some evidence of some widespread systemic response to the vaccine in order to really believe that this response would have spilled over and caused further exacerbation of what was already an immune response to a quite severe respiratory infection." Tr. 189-90. While Dr. Gershwin disagrees with Dr. Morel's statement that the cytokine reaction to the vaccine is not systemic, Tr. 91, he ultimately states that the issue of the systematic nature of the immune response is moot. He argues that since the lymph nodes where the cytokine response to the vaccine would occur are the same as the lymph nodes where the immune response to the URI would occur, the two responses have the opportunity to interact. Tr. 91-92. Dr. Morel does not challenge that there is a strong cytokine response to the vaccine in the lymph nodes, Tr. 190, and actually proffers exhibit HH to make that very point. See exhibit FF at 2 (citing exhibit HH (Nikolaos Chatziandreou, *Macrophage Death following Influenza Vaccination Initiates the Inflammatory Response that Promotes Dendritic Cell Function in the Draining Lymph Node*, 18 Cell Reports 2427 (2017)) to establish that "the majority of the cytokines produced by cells of the innate and adaptive immune system are confined to the lymph node").

While Dr. Morel did introduce persuasive epidemiological studies showing that there is not an association between hepatitis vaccines and GBS, those studies do not appear to inform the present case. See exhibit B at 4 (citing, e.g., exhibit O (Nizar Souayah et al., Analysis of Data from the CDC/FDA Vaccine Adverse Event Reporting System (1990-2009) on Guillain-Barre Syndrome after Hepatitis Vaccination in the USA, 19 J. Clinical Neuroscience 1089 (2012)) and exhibit U (Penina Haber et al., Vaccines and Guillain-Barré Syndrome, 32 Drug Safety 309 (2009)). As noted above, Dr. Gershwin does not claim that the hepatitis vaccine alone caused Mr. Eamick's GBS to develop. Instead, Dr. Gershwin argues that the vaccination explains why Mr. Eamick's URI induced a loss of tolerance, something that very few URIs do. An informative epidemiological study would have to examine the effects of hepatitis vaccination on individuals suffering from a URI (or perhaps other infections associated with GBS) to see if there were an increased risk of developing GBS. According to both experts, these studies have not been done and would be incredibly difficult to do given the sample size required. Tr. 97, 211.

Dr. Morel also challenges Dr. Gershwin's theory on the basis that there is a lack of evidence linking hepatitis vaccinations with GBS. However, it appears that she applies a burden that is in excess of the burden imagined by the Vaccine Act as interpreted by the Federal Circuit. Towards the end of her testimony, Dr. Morel summarized her opinion:

. . . there aren't any studies that have -- that describe the precise sequence of events that Mr. Eamick went through. All we can say is that, taken separately, we know that GBS is usually preceded by an upper respiratory tract infection and that hepatitis A and B vaccines, in general, do not cause that disease. So I think I'd just put those two facts together, and that's how I came up with my opinion.

Tr. 243. This statement reflects the undersigned's general impression that Dr. Morel and Dr. Gershwin primarily disagree about the sufficiency of the evidence necessary to draw their conclusions. As a physician and a scientist, Dr. Morel may find the evidence here to be insufficient to conclude that the hepatitis vaccinations can cause GBS under the right circumstances. However, the undersigned is not tasked with determining if the hepatitis vaccinations can cause GBS with anything approaching medical certainty. The only question is whether petitioner's theory meets the standards set forth by the Federal Circuit under Althen. On its face, Dr. Gershwin's theory is persuasive. Respondent has presented insufficient evidence

to undermine its reputability and thus Mr. Eamick has satisfied the first prong of the Althen analysis.

B. Althen Prong Three: Temporal Relationship between the Vaccination and the Injury.

Neither party focused on the issue of timing. Petitioner's pre-hearing brief dedicated a paragraph to the issue. See Pet'r's Preh'g Br., filed June 13, 2017, at 22. Respondent's brief dedicated two. See Resp't's Preh'g Br., filed July 13, 2017, at 17. However, the extent of respondent's argument was to say that petitioner did not sufficiently address the timing element. Id.

The limited time spent analyzing the question of timing is likely, in part, attributable to the fact that both parties agree that the timing between Mr. Eamick's URI and the onset of his GBS was consistent with a causal link existing between the two. Id. This fact is, in large part, the basis for the Secretary's argument that the URI completely accounts for Mr. Eamick's GBS. See Tr. 183; see also exhibit B at 3 (noting that the timing was appropriate).

However, as noted before, the point of disagreement between the parties is whether the vaccination was also a substantial factor. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) (indicating that a vaccination is the "legal cause" of an injury if the vaccination "is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the" vaccination). In his testimony, Dr. Gershwin points to the timing between the vaccination and the onset of GBS as indicating a causal relationship between the two.

To support this assertion, Dr. Gershwin explained that starting 24-48 hours after antigen exposure, immunoglobulin (Ig) that has been exposed to the antigen will begin to "class switch" from IgM to IgG. Tr. 100. This class switch would peak seven to ten days following antigen presentation. Id. This change to IgG is important because IgG can more easily pass through the blood brain barrier and result in the type of pathology seen in GBS. Tr. 199. Because Mr. Eamick's GBS symptoms appeared one week following his vaccination, Dr. Gershwin argues that this sequence is consistent with his medical theory that the cytokine response to the hepatitis vaccine played a substantial role in the development of Mr. Eamick's GBS. Tr. 100. The respondent's expert did not counter this argument. Accordingly, the evidence in the record favors a finding that there was an

appropriately proximate temporal relationship between the vaccination and the onset of Mr. Eamick's GBS.

C. Althen Prong Two: Logical Sequence of Cause and Effect Showing that the Vaccination was the Reason for Mr. Eamick's GBS.

Evidence of a viable medical theory and temporal proximity between the vaccination and the injury is strong evidence of causation. However, the Federal Circuit has also said that such evidence is not enough. Althen, 418 F.3d at 1278 (“[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation”). In Capizzano, the Federal Circuit further expounded upon the importance of evaluating whether a logical sequence of cause and effect exists independently of the timing analysis. Specifically, the Capizzano panel stated “[t]here may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine.” Capizzano, 440 F.3d at 1327. Thus, special masters must consider the whole picture and determine, on the basis of all the evidence, if the purported connection between the vaccination and the injury is logical. Examples of some of the evidence that special masters may consider here include the opinions of treating physicians and medical experts, evidence of rechallenge, epidemiological studies, and the probability of coincidence or another cause. See id. The evidence available to be weighed will, of course, depend on the facts of the case.

The parties did not present much evidence to be weighed under the second Althen Prong. See Pet'r's Preh'g Br., filed June 13, 2017, at 20-22; Resp't's Preh'g Br., filed July 13, 2017, at 15-17. In large part, the focus of both petitioner's and respondent's arguments under this prong of the analysis reverted to an examination of the underlying medical theory as well as the temporal relationship between the URI, the vaccinations, and the GBS. Id. These issues have been reviewed above.

In addition, respondent points out that no treating physician associated Mr. Eamick's GBS to his vaccinations. Resp't's Preh'g Br., filed July 13, 2017, at 15; Tr. 125. While this observation weighs against the conclusion that there exists a logical connection between the vaccinations and the disease, the weight of this evidence is not substantial. For one, as reviewed above, it is unknown why some URIs trigger GBS and others do not. Accordingly, the physician would merely be

speculating and this lack of speculation in the medical records does not strike the undersigned as particularly meaningful. Second, Dr. Gershwin's opinion that the association between Mr. Eamick's vaccination and his development of GBS is logical is given substantial weight. As noted before, Dr. Gershwin's testimony was particularly credible and his argument for the logical basis between the vaccination and the injury was persuasive. See Section II.C.

D. Alternative Causation or Factor Unrelated

Even though Mr. Eamick has established his prima facie case under Althen, the Secretary may still establish by preponderant evidence that his GBS is due to factors unrelated to the vaccinations, thus precluding compensation. See Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing 42 U.S.C. § 300aa-13(a)(1)(B)). To do so, respondent must "provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury." Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1354 (Fed. Cir. 2008).

Here, the Secretary argues that Mr. Eamick's URI is the sole substantial factor in bringing about his GBS and that this should preclude compensation. Resp't's Preh'g Br., filed July 13, 2017, at 10, 16. In doing so, respondent cites to Tompkins v. Sec'y of Health & Human Servs., No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), mot. for rev. denied, 117 Fed. Cl. 713 (2014). The respondent is correct in noting that the facts in Tompkins are quite similar to the facts of Mr. Eamick's case. Thus, it is not surprising that the respondent points to Special Master Vowell's conclusion that Mr. Tompkins's preceding respiratory infection was the cause of his GBS, precluding compensation. Id. at *1 ("I find that his upper respiratory infection, which began two weeks prior to the onset of his GBS symptoms, is a well-recognized cause of GBS, occurred at an appropriate temporal interval before onset of symptoms, and is the most likely cause for [petitioner's] GBS").

As a preliminary note, "[i]t is well-settled that special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims" Rickett v. Sec'y of Health & Human Servs., 468 F. App'x 952, 959 (Fed. Cir. 2011) (citing Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999)). Furthermore, the Federal Circuit has explicitly noted that special masters may very well come to different conclusions based on the same set of facts. Lampe v. Sec'y of Health & Human Servs., 219

F.3d 1357, 1368 (Fed. Cir. 2000). But of course, the facts here, though similar, are not identical. For example, Mr. Eamick relied upon a different expert — one that, as stated in Section II, made a persuasive case in support of Mr. Eamick's claim.

But, even more, Mr. Eamick did not rely on the same theory proffered by Mr. Tompkins. As reviewed in Section IV.A, above, petitioner does not dispute that the URI was necessary for Mr. Eamick's GBS to develop. He does dispute, however, that it was sufficient. Mr. Eamick supports this assertion by demonstrating that the vast majority of URIs *do not* develop into GBS and that it is currently believed that host factors, and not the preceding infection itself, are critical in determining whether a URI will cause GBS. See exhibit 51 (Hadden) at 7. Dr. Gershwin proposes a cytokine response to hepatitis vaccination as constituting this host factor in Mr. Eamick's case and, for the reasons stated above, this explanation appears persuasive. Based on the evidence in the record, it does not appear that the respondent presents an alternate explanation for why Mr. Eamick's URI caused the onset of his GBS when the vast majority of URIs do not. While it may be true that most cases of GBS are preceded by an infection, it is not true that most infections are followed by GBS. Clearly, there is more to the story. In this way, the absence of an alternate host factor that may have induced the onset of GBS in Mr. Eamick's case actually weighs in petitioner's favor.

V. Conclusion

As the Federal Circuit has noted, cases in the Vaccine Program often have to navigate an area of science bereft of certainty and absolutes. We, as a society, can only hope to one day know why Mr. Eamick developed GBS, and a particularly virulent form of the disease at that. Until that time, the Federal Circuit has stated that compensation is appropriate when a petitioner can provide evidence of a reputable medical theory attributing petitioner's injury to the vaccination, evidence of an appropriately proximate temporal relationship between the two, and evidence that the causal association is logical. Mr. Eamick has met this standard and, therefore, is entitled to compensation under the Vaccine Act.

An order regarding damages will be issued shortly.

s/ Christian J. Moran
Christian J. Moran
Special Master